MEDICAL DEVICE GUIDANCE

GN-35: Guidance on Special Access Routes (SAR)

Revision 4

Jan 2023

CONTENTS

1. **Introduction**
2. **Application Requirements**
3. **Application Process**
   i. Online procedure
   ii. Points to Note
4. **Post-market Obligation**
5. **Declaration on Distribution Records**
6. **Appendix**
   i. Summary of routes
   ii. Definitions
   iii. Templates

REVISION HISTORY

Guidance Version (Effective Date) *[3 latest revisions]*	Revision
GN-35: Guidance on Special Access Routes (SAR): Revision 1 (19 Oct 2019)	R1
R2 ► Guidance on Special Access Routes (SAR): Revision 2 (March 2022)	R2
R3 ► Guidance on Special Access Routes (SAR): Revision 3 (08 Aug 2022)	R3
R4 ► Guidance on Special Access Routes (SAR): Revision 4 (11 Jan 2023)	R4

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown*

INTRODUCTION

- Under the Health Products Act (Act) and Health Products (Medical Devices) Regulations 2010 (Regulations), **all** Class B, C and D medical devices are required to be registered with HSA prior to placing them on the Singapore market.

- In an emergency or in a case where all conventional therapies have failed, qualified practitioners (i.e. doctors and dentists) may need access to unregistered medical devices to meet special clinical needs (refer to Table 1) arising in the course of their practice.

- Special access routes may be used to enable qualified practitioners to access unregistered medical devices for use on their patients.

Table 1: Definition of Special Clinical Needs

Medical devices on compassionate use basis

- ❑ Absence of alternative treatment option; or
- ❑ Available alternative treatments failed or deemed ineffective or unsuitable for the patient according to the doctor's or the dentist's clinical judgement;

and

- ❑ Patient's health will be clinically compromised without the requested treatment

Alleviation of stock-out situation

- ❑ The unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device

Established medical devices with history of use

- ❑ The unregistered medical device has been used
  - ➢ before 1 January 2012
  - ➢ in a licensed private hospital as approved by the relevant authority of that healthcare facility; or
  - ➢ in a licensed medical clinic as required by the doctor or dentist,

and

- ❑ There are no known safety issues related to the use of the device

Novel or established medical device or upgraded version of established medical devices (new models/ new features)

- ❑ Absence of registered alternatives or lack of a specific feature in registered medical device; or
- ❑ User's (doctor or dentist) familiarity or expertise in terms of device technology, design and/or operation that is likely to support or enhance the safety outcomes of the procedure or treatment for the patient;

and

- ❑ Patient's health will be clinically compromised without the requested medical device.

INTRODUCTION

The following special access routes may be used to facilitate the import and supply of unregistered medical devices for **clinical use**:

GN-26

R2 ►
- For licensed **qualified practitioners** to seek approval for the import and supply of **unregistered** medical devices for use on his patient.

GN-27

- For **healthcare facilities licensed under the Private Hospitals and Medical Clinics Act (PHMCA) / Healthcare Services Act (HCSA)** to seek approval for the import and supply of **unregistered** medical devices for use on their patients. ◄

IMPORTANT

- ❑ The safety, quality and performance of the device is **not assessed** by HSA during application review.
- ❑ As such, **the responsibility for prescribing an unregistered medical device rests with the qualified practitioner.**

R3 ►
- ❑ The qualified practitioner should also ensure the **patient is appropriately informed prior to treatment and consents to the treatment***. ◄

**the doctor has discretion on the format used for this process*

INTRODUCTION

GN-26 and GN-27 applications with Class C and D medical devices for Public Healthcare Institutions

R2► As part of HSA's efforts to strengthen our regulatory oversight on import of higher risk unregistered medical devices for local clinical use, additional safeguard measures* are required to ensure these devices are used to meet genuine clinical services needs.

1. Endorsement of SAR application by Chairman of Medical Board (CMB) of the Public Healthcare Institution (PHI) or equivalent

- ❑ If the GN-26 or GN-27 application contains unregistered **Class C and/ or Class D** medical devices, endorsement by **CMB of the PHI or equivalent** is required.

**Please note that the additional safeguard measures will not apply to requests from private healthcare facilities for unregistered class C and D medical devices at the moment. HSA and MOH will track and review requests for these higher risk medical devices from the private healthcare facilities and introduce additional safeguard measures as required at a later date.*

◄

R2►

2. Review of clinical justification by Ministry Of Health (MOH) for Class D medical devices

For the following specific categories of Class D medical devices:

a. ***New technologies and state-of-the-art medical devices for clinical use*** on patients, including novel indications for existing medical devices or technologies.They can expose healthcare professionals and patients to significant risks as these unregistered medical devices have not been reviewed by HSA for their safety and effectiveness.

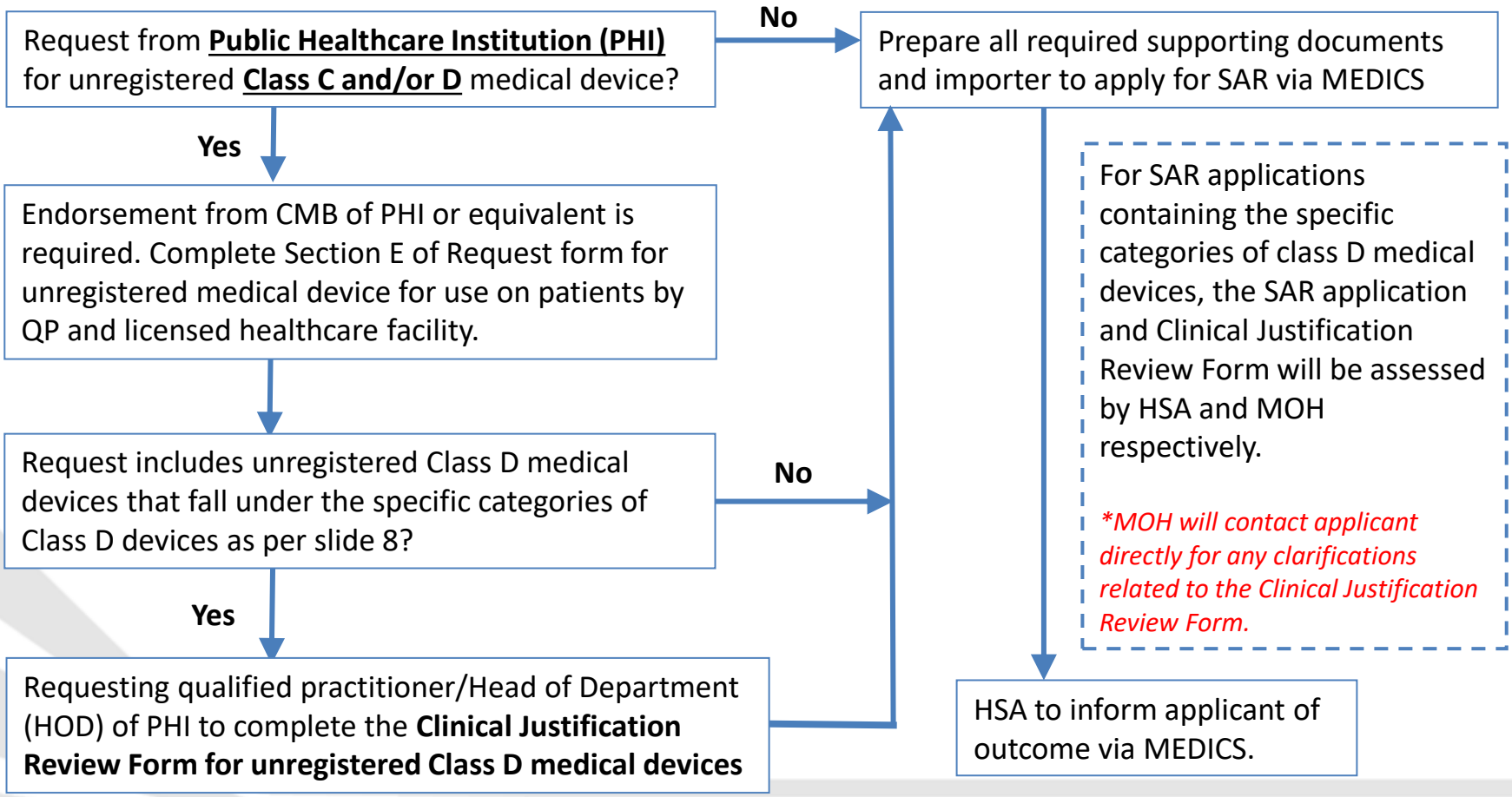
b. ***Unregistered implants*** (e.g., pacemakers, breast implants) as implants can fail post surgery, and give rise to long term complications, e.g., repeat or revision surgeries, or other clinical interventions that are likely to expose patients to further risks/complications.

- ❑ Applicable only to **PHIs** that apply for unregistered **Class D** medical devices.
- ❑ Requesting qualified practitioner/Head of Department (HOD) of the PHI shall complete the **Clinical Justification Review Form for unregistered Class D medical devices** available on the HSA website.
- ❑ Completed form shall be uploaded and submitted together with the rest of the supporting documents via MEDICS

◄

R2►

Flowchart: Request for unregistered medical devices for local clinical use



INTRODUCTION

Special access routes may also be used to facilitate the import and supply of unregistered medical devices for export, re-export or non-clinical purposes, as described below.

GN-28

- For the import of **unregistered** medical devices for the purposes of **export or re-export**

Note:

- *Companies with existing importer and wholesaler licences shall not require GN-28 authorisation for import for re-export.*
- *Dealers shall be required to maintain documentary evidence of import and supply (e.g. traceability records) as part of their mandatory device distribution records.*
- *Medical devices manufactured in Singapore and that are solely for export shall not require GN-28 authorisation from HSA for their export by the licensed manufacturer*

GN-29

- For the import of **unregistered** medical devices for **non-clinical purposes**

Note: Non-clinical purposes includes any form of use other than use or administration on humans e.g. training equipment (i.e. Not for use on humans); use on animals; or use of in-vitro diagnostic medical devices for research-use only.

GN-30

- For the import of **registered** medical devices on **a consignment basis**, by dealers not authorised by the Registrant

Note: The importation of a medical device which is already registered on the Singapore Medical Device Register (SMDR) shall be performed by a licensed importer authorised by the Registrant only. A dealer who has not been authorised by the Registrant to import a registered medical device may seek authorisation from HSA through this route.

APPLICATION REQUIREMENTS

Supporting documents

The supporting documents to be submitted for each route is detailed below.

Supporting documents	GN-26	GN-27	GN-28	GN-29	GN-30
SAR Device List (Appendix 3) R2► ***Note:*** *for GN-26/27 applications with class C/D devices, please highlight these higher risk medical devices in the SAR device list and re-attach in MEDICS as a separate supporting document to facilitate verification* ◄	√	√	√	√	√
Instructions for Use, Product Insert, or Operations Manual by the product owner	√	√		√	√
Primary medical device label	√	√		√	√
A copy of the qualified practitioner's registration under the Medical Registration Act (Cap. 174) or Dentists Act (Cap. 76) with the Medical Council Registration (MCR) Number or Dental Council Registration (DCR) Number clearly legible	√				

APPLICATION REQUIREMENTS

Supporting documents

Supporting documents	GN-26	GN-27	GN-28	GN-29	GN-30
R2► A copy of the PHMC/ HCSA Licence of the requesting healthcare facility, with the Licence Number clearly legible. ◄		√			
A copy of quality management system certificate (e.g. Good Distribution Practice for Medical Devices (GDPMDS)) if a valid Importer licence with GDPMDS is unavailable	√	√			
Request form for unregistered medical device for use on patients by QP and licensed healthcare facility (Appendix 4) *Note: clinical justification shall reflect special clinical need (Table 1).*	√ by requesting qualified practitioner	√ by HOD or equivalent representing the licensed healthcare facility			
R2► Clinical Justification Review Form for unregistered Class D medical devices (Appendix 4.1) **(For Public Healthcare Institutions only, for specific categories of Class D medical devices)** ◄	√ by requesting qualified practitioner	√ by HOD or equivalent representing the licensed healthcare facility			

APPLICATION REQUIREMENTS

Supporting documents

Supporting documents	GN-26	GN-27	GN-28	GN-29	GN-30
Label with a statement 'for supply for non-clinical purpose only'				√	
SMDR listing number of the original registered medical device					√
Documentary evidence to show that the medical device is registered in the exporting country e.g. free sale certificate					√
Certified true copy of ISO 13485 certificate for each of the manufacturing sites					√

APPLICATION REQUIREMENTS

Supporting documents

Supporting documents	GN-26	GN-27	GN-28	GN-29	GN-30
Copy of invoice from exporting company indicating the lot number/serial number of each of the medical device to be imported					√
Attestation from product owner that the medical device is identical to registered medical device in Singapore, including the manufacturing site, packaging and labelling (Appendix 5)					√
Undertaking by importer to take responsibility for quality, safety and performance of the medical device to be imported					√

APPLICATION PROCESS

Online procedure

All **Special Access Route (SAR)** transactions are conducted through the Medical Device Information and Communication System (MEDICS)

Importer to apply for CRIS Company Account

- A CRIS account allows companies to carry out electronic transactions with HSA
- Refer to Client Registration and Identification Service (CRIS) here

Importer to prepare and apply for SAR via MEDICS

- Obtain **all** required supporting documents
- Refer to Table 2 for importer pre-requisite requirements
- Refer to MEDICS application guide for Special Access Route

R2► ***Note:** Only the **importer** of the device may submit the SAR application* ◄

Review of application by HSA

- Turn-around-time (TAT): 14 working days*

R4► * Please note that for applications that include class D medical devices that fall under the specific categories of Class D devices that require review by MOH, the TAT will be extended by 14 working days. ◄

APPLICATION PROCESS

Online procedure

Table 2: Pre-requisite requirements

R2►

SA route	Eligibility criteria	Importer pre-requisite requirements
GN-26 **GN-27**	Unregistered medical device that has obtained **at least one** reference regulatory agency approval. •Australia Therapeutic Goods Administration (TGA) •Health Canada (HC) •Japan Ministry of Health, Labour and Welfare (MHLW) •US Food and Drug Administration (US FDA) •European Union Notified Bodies (EU NB)	A certified quality management system (e.g. to the requirement of Good Distribution Practice for Medical Devices (GDPMDS))
GN-30	The medical devices registered on Singapore Medical Device Register (SMDR)	A valid importer and wholesaler licence with Good Distribution Practice for Medical Devices (GDPMDS) or ISO 13485

◄

The full application fees will be charged upon submission of the application in MEDICS. Payment is to be made by the applicant (i.e. importer).

- Acceptable payment modes: Credit card or GIRO
- Download the GIRO application form here if you wish to set up a GIRO account with HSA
- Refer to the fee schedule on HSA website for the applicable fees

NOTE:

- Once the application has been submitted, there shall be **no refund of application fees.** This includes any incorrect or withdrawn applications R2► e.g. due to changes in importer and wholesaler information. ◄
- There shall be **no amendments** to the application, including the quantity requested for use, once the application has been approved. A new submission will be required.

APPLICATION PROCESS

Points to note

- It is the responsibility of the licence holder, licensed healthcare facility and qualified practitioner/user to ensure the medical device(s) complies with any other applicable regulatory requirements of other regulatory bodies in Singapore prior to its supply or for its use.
  - *E.g. for medical devices also subject to control under the Radiation Protection Act, a licence from the Radiation Protection and Nuclear Science Department (RPNSD) of the National Environment Agency (NEA) may be required.*
- The safety and performance of the device is **not assessed** by HSA during application review.
- The authorisation shall only be valid for a period of **12 months** from the date of approval, and permits multiple import consignments within the validity period (except GN-30 which only permits a single import consignment).
- The unregistered medical device shall only be imported by the importer authorised in the approval.
- **No further import and supply of the medical devices is permitted after expiry of the authorisation**. Unauthorised supply of an unregistered medical device is an offence under the Act and penalties of a fine of up to $50,000 or imprisonment for a term not exceeding 2 years, or both will apply.

APPLICATION PROCESS

Points to note

GN-26 & GN-27 applications

- HSA requires that applications be **substantiated with a clinical justification**, reflecting the **special clinical need** (Table 1) for the unregistered devices by the qualified practitioner (for GN-26) or Head of Department or equivalent representing the licensed healthcare facility (for GN-27) in place of registered products.
- Capital equipment **shall not** be authorised via GN-26 and GN-27. Product registration will be required.
  - *Refers to medical devices that are installed as part of the PHMC's fixed infrastructure e.g. X-ray machines, CT scanners, MRI machines.*
- Records on the particulars of patients are to be maintained and kept on file by the requesting qualified practitioner or licensed healthcare facility and to be submitted upon request by the Authority.

R2►

IMPORTANT:

- **Companies intending to supply these medical devices on a long term basis should register these devices.**
- **Supply of unregistered single use medical devices and implants, including administration or use on patients by licensed healthcare facility or QP shall not be permitted after the authorisation expires.**

◄

POST-MARKET OBLIGATION

The responsibility for reporting field safety corrective actions (FSCA) and adverse events (AEs) for medical devices that are supplied through the Special Access Route (SAR) lies primarily with the importer who arranged for its supply.

It is a condition of approval that the importer reports the details of any FSCA or adverse event to the Authority according to applicable timelines.

R2► Qualified practitioners (QPs) and healthcare facilities can report AEs for medical devices via the voluntary adverse event e-form (mobile-friendly).

For more information on AEs reporting of medical devices, please visit https://www.hsa.gov.sg/medical-devices/adverse-events ◄

DECLARATION ON DISTRIBUTION RECORDS

- The importer shall be required to submit a declaration on the distribution records via MEDICS within 30 days after expiry of authorisation, or within 30 days after date of last export/supply*, whichever is earlier.

- Importer shall be required to maintain documentary evidence of supply (e.g. traceability records) as part of their mandatory device distribution records for the devices imported under this authorisation. This information shall be submitted to the Authority upon request.

**refers to delivery of the medical device to qualified practitioner, healthcare facility or the consignee using it for non-clinical purpose.*

APPENDIX 1

Summary of routes

	GN-26	GN-27	GN-28	GN-29	GN-30
Description	For licensed qualified practitioner to seek approval for the import and supply of unregistered medical devices for use on his patient.	For laboratories and medical facilities licensed under the PHMCA / HCSA to seek approval for the import and supply of unregistered medical devices for use on their patients.	For the import of unregistered medical devices for the purposes of export or re-export	For the import and supply of unregistered medical devices for non-clinical purpose	For the import of registered medical devices on a consignment basis, by dealers not authorized by the Registrant
R2 ► Eligibility criteria	Unregistered medical device that has obtained at least one reference regulatory agency approval i.e. HC, MHLW, US FDA and TGA, EU NB.	Unregistered medical device that has obtained at least one reference regulatory agency approval i.e. HC, MHLW, US FDA and TGA, EU NB.			The medical devices shall be registered on Singapore Medical Device Register (SMDR)
Pre-requisite requirement for the importer	A certified quality management system (e.g. to the requirement of Good Distribution Practice for Medical Devices (GDPMDS))	A certified quality management system (e.g. to the requirement of Good Distribution Practice for Medical Devices (GDPMDS))			A valid importer and wholesaler licence with Good Distribution Practice for Medical Devices (GDPMDS) or ISO 13485

APPENDIX 1

Summary of routes

	GN-26	GN-27	GN-28	GN-29	GN-30
Validity period	12 months	12 months	12 months	12 months	12 months
No. of import consignments allowed	Multiple	Multiple	Multiple	Multiple	Single
Fees	Refer to the fee schedule on HSA website for the applicable fees				

APPENDIX 2

Definitions

IMPORT: with its grammatical variations and cognate expressions, means to bring or cause to be brought into Singapore by land, sea or air.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the Act. This includes IN VITRO DIAGNOSTIC (IVD) PRODUCT (as set out in the Regulations).

PRODUCT OWNER: (as set out in the Regulations):

- in relation to a health product, means a person who —
- (a) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
- (b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

QUALIFIED PRACTITIONER (as set out in the Regulations) : means:-

- a person registered under the Medical Registration Act (Cap. 174), when acting in the course of providing medical treatment to a patient under his care; or
- a person registered under the Dentists Act (Cap. 76) whose name appears in the first division of the dentists register kept under that Act, when acting in the course of providing dental treatment to a patient under his care.

APPENDIX 3

SAR List of Devices

SPECIAL ACCESS ROUTE								
DEVICE LIST								
Overall System Name *(If the MDs do not have any overall system name, enter the name as per device label as indicated in Column D.)*	**Name as per device label** *(To include software version number, if applicable, for supply in Singapore)*	**Identifier**	**UDI-DI** *(To use ";" if there are multiple UDI-DI per identifier)*	**DM-DI (Only if DM-DI is available and is different from UDI-DI)** *(To use ";" if there are multiple UDI-DI per identifier)*	**Maximum Quantity** *(For GN-27 application with multiple PHMC facilities, please input the total consolidated quantity requested by all PHMC facilities.)*	**Unit of Measurement (UOM)** *(pieces, units, vials, boxes etc. If the UOM is in boxes, please state the quantities found in each box)*	**Any Approval from Reference Agencies? Y/N** *(US FDA, EU, Health Canada, Australia TGA, Japan MHLW)*	**Filenames of labels** *Please identify all variable fields if representatives lab submitted. For GN-28: Indicat*

APPENDIX 4

Request form for unregistered medical device for use on patients by QP and Licensed Healthcare Facility

MEDICAL DEVICES CLUSTER

REQUEST FOR UNREGISTERED MEDICAL DEVICE FOR USE ON PATIENTS BY QUALIFIED PRACTITIONER/ LICENSED HEALTHCARE FACILITY

* Please complete all fields below. All fields are mandatory.

Section A: Purpose of application

- ○ GN-26: On request by Qualified Practitioner for use on his patient
- ○ GN-27: On request by licensed healthcare facility for use on their patients

Section B: Requesting Qualified Practitioner (QP) information

To be completed by Head of Department (or equivalent) of licensed healthcare facility for GN-27.

Full name		MCR or DCR Number	
Department		Designation	
Email		Tel no	
Name of Hospital/Clinic			
PHMC/ HCSA Licence No			
Address			

Section C: Clinical justification

Please select the appropriate clinical justification(s):

- ☐ Absence of alternative treatment option
- ☐ Available alternative treatments failed or deemed ineffective or unsuitable for patient according to professional judgement
- ☐ Unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device
- ☐ Absence of registered alternatives or lack of a specific feature in registered medical device
- ☐ User's (doctor or dentist) familiarity or expertise
- ☐ Established medical device with history of safe use in a licensed private hospital or medical clinic

Please provide elaboration on the basis for the above selection:

☐ Clinical Justification Review Form for unregistered Class D medical devices is included in this application

Section D: Declaration

IMPORTANT

1. I am fully aware that the medical device(s) specified in **attached SAR Device List** has not been evaluated by the Authority for the required quality, safety and efficacy standards for supply in Singapore.
2. The import and/or supply of the unregistered medical device(s) are required for the use of the patient(s) under my care/ patients of the licensed healthcare facility and I undertake to assume full responsibility for such use.
3. I undertake to ensure the patient is appropriately informed prior to treatment and consents to the treatment.
4. I undertake to maintain records of the patient including the contact details of the patient who received the above medical device(s) under my care/ the care of the licensed healthcare facility.
5. I will ensure that this medical device will be used or administered in accordance to its intended purpose and indications for use as stated in the product owner's instructions for use.
6. I undertake to indemnify the government against all actions, claims or proceedings in respect of any adverse event, injury to or death of any person whomsoever arising out of or in connection with the use of the above unregistered medical device.
7. I hereby declare that all the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.

Date _____ Signature of Qualified Practitioner/ Head of Department _____

Page 1 of 2

APPENDIX 4

Request form for unregistered medical device for use on patients by QP and Licensed Healthcare Facility (continued)

Complete the below sections if the application is requested by a public healthcare instituition (PHI) and contain Class C and/ or Class D medical devices.

Section E: Endorsement by Chairman of Medical Board (CMB) or equivalent.

Full name		MCR or DCR Number	
Department		Designation	
Email		Tel no	
Name of Hospital/Clinic			
PHMC/ HCSA Licence No			
Address			

IMPORTANT

☐ I support the request of the unregistered Class C and/or Class D medical devices in this application

1. I am fully aware that the medical device(s) specified in **attached SAR Device List** has not been evaluated by the Authority for the required quality, safety and efficacy standards for supply in Singapore.
2. The import and/or supply of the unregistered medical device(s) are required for the use of the patients of the licensed healthcare facility.
3. I hereby declare that all the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.

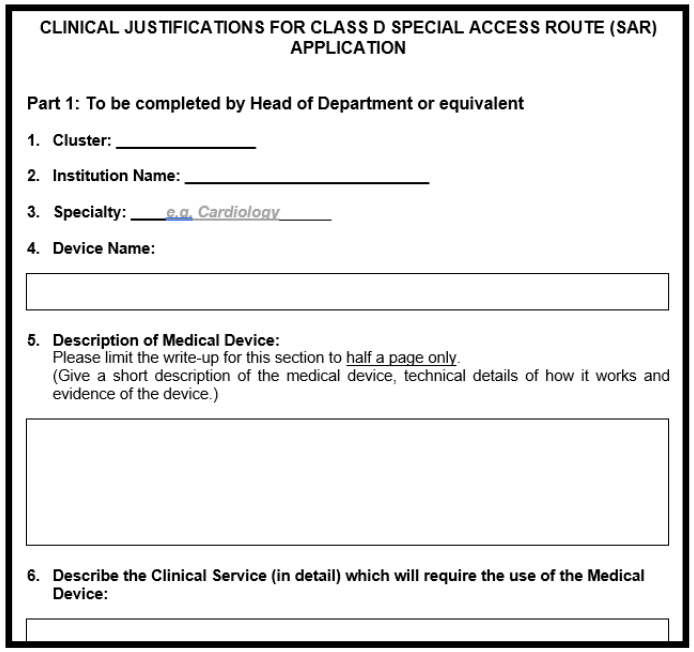
Date _____ Signature of CMB or Equivalent _____

NOTE:

- A copy of "SAR Device List" shall be provided to the **QP/HOD and CMB/equivalent of PHI (if applicable)** signing off the forms.
- The signed document shall be **scanned** and submitted to HSA via MEDICS.
- The original signed hardcopy form **shall be maintained and kept on file** by the applicant. This information shall be submitted to the Authority upon request.

APPENDIX 4.1

Clinical Justification Review Form for unregistered Class D medical devices *for Public Healthcare Institutions*



CLINICAL JUSTIFICATIONS FOR CLASS D SPECIAL ACCESS ROUTE (SAR) APPLICATION

Part 1: To be completed by Head of Department or equivalent

1. **Cluster:** _____
2. **Institution Name:** _____
3. **Specialty:** ____*e.g. Cardiology*_____
4. **Device Name:**

5. **Description of Medical Device:**
   Please limit the write-up for this section to half a page only.
   (Give a short description of the medical device, technical details of how it works and evidence of the device.)

6. **Describe the Clinical Service (in detail) which will require the use of the Medical Device:**

NOTE:

- A copy of "SAR Device List" shall be provided to the **QP and CMB/equivalent of PHI** signing off the forms.
- The signed document shall be **scanned** and submitted to HSA via MEDICS.
- The original signed hardcopy form **shall be maintained and kept on file** by the applicant. This information shall be submitted to the Authority upon request.

Letter of Authorisation Template

[To be printed on Company Letterhead of Product Owner]

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for *[name of Importer]*

We, *[name of Product Owner]*, as the Product Owner, hereby confirm that the medical devices listed below have been manufactured to the same safety, quality and performance specifications as the medical device listed under Singapore Medical Device Register (SMDR) listing number, *[device listing number].*

[List containing the following: (i)product names of medical devices for import, (ii) quantity for import, (iii) manufacturing site, (iv) ISO 13485:2003 certificate number,(v) SMDR listing number, (vi) invoice number (vii) invoice date]

We hereby acknowledge that we are aware of the import of the medical devices listed above into Singapore by *[name of Importer]* for the quantity specified. We shall keep *[name of Importer]* informed of any Field Safety Corrective Action (FSCA) that is applicable.

Yours Sincerely,

[Signature]
[Full Name and Title of Senior Company Official]
[Name and address of company]

CONTACT INFORMATION

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg